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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,330	01/05/2005	Hiroyuki Hamada	10873.1598USWO	5251
7590 01/16/2007 HAMRE SCHUMANN MUELLER & LARSON PC PO Box 2902-0902 Minneapolis, MN 55402			EXAMINER MARTIN, PAUL C	
			ART UNIT	PAPER NUMBER
			1657	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/16/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No. 10/520,330	Applicant(s) HAMADA ET AL.	
	Examiner Paul C. Martin	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 4 and 7-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, and 7-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 3, 4, and 7-13 are pending in this application and were examined on their merits.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/13/06 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 4 and 7-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 9 contain the language "...repeatedly performing fluid infusion and fluid drain of a predetermined amount of peritoneal dialysis fluid in alternation for peritoneal dialysis fluids having different osmotic pressures." It is unclear whether the fluid infusion and drain steps are performed with two different dialysis fluids one right after the other (ex. A-B-A) or in alternate series (ex. A-A-B-B). Claims 3, 4, and 7-13 are rejected for being dependent upon rejected claims 1 and 9.

Claims 1, 3, 4 and 7-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 9 contain the language, "...and a concentration of monitored solutes in the peritoneal dialysis fluid." It is unclear whether the analysis of the drain fluid in the previous lines to determine the amount of peritoneal dialysis fluid retained within the abdominal cavity of the patient also encompasses the analysis of monitored solutes, or whether a separate analysis step is performed. Claims 3, 4, and 7-13 are rejected for being dependent upon rejected claims 1 and 9.

Claims 1, 3, 4 and 7-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 9 contain the language, "performing a peritoneal equilibrium test".

It is unclear on what or whom the peritoneal equilibrium test is being performed, and what steps are encompassed in performing the peritoneal equilibrium test. Claims 3, 4, and 7-13 are rejected for being dependent upon rejected claims 1 and 9.

Claims 1, 3, 4 and 7-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 9 contain the language, "performing a blood test in order to assess a change in condition in the blood due to performing fluid infusion and fluid drain." It is unclear how any change in blood will be assessed as Claims 1 and 9 further state that "the step of performing the blood test is executed only once". How one will assess a change with no basis for comparison is unclear to the Examiner. Further, it is unclear what is meant by a change in "condition in the blood", as the condition could be any number of variables such as temperature, pH, solute concentration, chemical composition, etc. Claims 3, 4, and 7-13 are rejected for being dependent upon rejected claims 1 and 9.

Claims 1 and 9 recite the limitation "dialysis fluid of respective osmotic pressure" and "dialysis fluid having the same osmotic pressure" in lines 13 and 15. There is insufficient antecedent basis for this limitation in the claim.

It cannot be determined which dialysis fluid in claim 1 is indicated as both respective and having the same osmotic pressure, as Claims 1 and 9 also state peritoneal dialysis fluids having different osmotic pressures in lines 4-5 of the claims. Claims 3, 4, and 7-13 are rejected for being dependent upon rejected claims 1 and 9.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3, 4 and 7-9 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Chen *et al.* (US 5,670,057) in view of Milner (US 6,077,836) and Kelton *et al.* (1978), for reasons of record set forth in the Action mailed 04/21/06 (and extended to new claims 10-13 as necessitated by the Applicant's amendment filed 09/21/06).

Applicant's arguments filed 09/21/06 have been fully considered but they are not deemed to be persuasive.

Response to Arguments

The Applicant argues that although Milner teaches the repeated infusion and drain of two alternate peritoneal dialysis fluids having different osmotic pressure, Milner does not disclose, teach or suggest, the step of performing at least three fluid infusion and fluid drains using dialysis fluids with the same osmotic pressure with the dwell times being different each time (Remarks, Pg. 8, Lines 11-19), further the Applicant argues that the combination of Kelton *et al.* with Chen *et al.* and Milner would not meet the new limitations of Claims 1 and 9 (Remarks, Pg. 8, Lines 20-23).

The Applicant's arguments are not persuasive for the following reasons, as stated in the prior Office Action mailed 04/21/06, Milner clearly discloses a method wherein the fluid drain and fluid infusion is performed at least three times for each of two dialysis fluids with different osmotic pressures (1.36% glucose and 5% glucose polymers) wherein the dwell times are different each time when using a dialysis fluid having the same osmotic pressure (6hrs, 8 hrs and 12hrs) See Milner, Column 9, Lines 1-30. Further, it is inherent that as the infusion and drains are performed by hand the exact times of infusion and drains at 6hrs for both the 1.36 glucose and 5% glucose polymer solutions would not occur at exactly the same time, and would therefore occur at *different* times. Therefore, the combination of Chen *et al.* with Kelton *et al.* and Milner still anticipates Claim 1 and 9 as amended.

Conclusion

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin
Examiner
Art Unit 1657

PATRICIA LEITH
PRIMARY EXAMINER



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